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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,897	09/05/2003	Joel W. Schwartz	VBLT:014US	1548

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EXAMINER

WEGERT, SANDRA L

ART UNIT	PAPER NUMBER
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1647

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/656,897

Applicant(s)

SCHWARTZ ET AL.

Examiner

Sandra Wegert

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 17, 18, 21 and 22 is/are rejected.
- 7) ☒ Claim(s) 12-16 and 19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments, and/or Claims

The Response received 22 November 2006 and the amendment received 25 January 2007 have been entered. Claims 23 and 24 are canceled. Claim 20 remains withdrawn, pending an allowance of the claimed invention. Claims 1-19, 21 and 22 are under examination.

Withdrawn Rejections

Claim Rejections - 35 USC § 112, first paragraph - scope of enablement

The rejection of Claims 12, 14-16 and 19 under 35 U.S.C. 112, first paragraph, for overly-broad scope, is *withdrawn* based on Applicants' arguments (22 November 2006). The rejection is maintained for 1-11, 17, 18, 21 and 22 as explained below.

New/Maintained Objections and/or Rejections

Claim Objections

Claim 12-16 and 19 are objected to as being dependent upon rejected base claims, but would be allowable if rewritten in independent form including all of the limitations of the base claims and any intervening claims.

Claim Rejections- 35 USC § 112, first paragraph - scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process

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of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 17, 18, 21 and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of using 4-(4-dimethylaminostyryl)-N-methyl- pyridinium (ASP⁺) to measure transporter activity of monoamine transporters, such as *NET*, *DAT* and *SERT*, does not reasonably provide enablement wherein ASP⁺ is used to measure the activity of other neurotransmitter transporters. The reasons for this rejection under 35 U.S.C. § 101 were set forth at pp. 2-4 of the previous Office Action (30 October 2006). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claims 1-11, 17, 18, 21 and 22 are drawn to methods of measuring the activity of a transporter as well as using the transporter to screen for agents that modulate the transporter. The specification discloses experiments in which the activity of *NET* was measured in the presence of the artificial substrates APP⁺ and MPP⁺ in several transfected cells and in one cell line that expresses *NET* endogenously (Figures 1 and 8A, respectively). Experiments were also described in which it was shown that ASP⁺ competes with norepinephrine (NE) transport. Additional studies showed that ASP⁺ accumulation is sensitive to cocaine and desipramine.

Applicants argue that the claimed subject matter should be expanded to include other monoamine transporters, such as *DAT* and *SERT*, and cite two recent publications by applicants (Mason, et al, 2005, J. Neurosci. Methods, 143: 3-25; Schwartz, et al, 2003, J. Biol. Chem., 278(11): 9768-9777, both submitted 11/22/2006) as evidence that ASP⁺ can be used to study the kinetics of monoamine transporters besides *NET*. Such methods are also contemplated in the instant Specification (page 3, for example).

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The evidence provided by applicants is convincing for claims 12-16 and 19. However, applicants have not argued as to why transporters other than monoamine transporters should be included in the methods, as encompassed by Claims 1-11, 17, 18, 21 and 22. Claims 1-11, 17, 18, 21 and 22 recite use of ASP⁺ to measure neurotransmitter transport in essentially all cells that transport *any* neurotransmitter. This would include transporters that are very different from monoamine transporters, such as acetylcholine transporters. Such transporters almost surely do not bind ASP⁺, since there is no evidence that they do, and because ASP⁺ is a monoamine-like ligand (i.e., it resembles tyrosine and tryptophan).

Due to the large quantity of experimentation required to determine how to use ASP⁺ in conjunction with transporters other than monoamine transporters, the lack of direction or guidance in the specification regarding same (e.g., the lack of guidance regarding transporter experiments using ASP⁺ with non-monoamine transporters), the lack of working examples that read on use of other transporters, the state of the art showing that neurotransmitter transporters differ in their substrate specificities (cited previously, 30 October 2006), and the breadth of the claims which embrace several unrelated transporters - undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Conclusion

Claims 1-11, 17, 18, 21 and 22 are rejected. Claims 12-16 and 19 are objected to.

THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Wegert whose telephone number is (571) 272-0895. The examiner can normally be reached Monday - Friday from 9:00 AM to 5:00 PM (Eastern Time). If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SLW

23 April 2007

A handwritten signature in black ink, reading "Eileen B. O'Hara". The signature is written in a cursive style with a large initial "E".

EILEEN B. O'HARA
PRIMARY EXAMINER